

REMARKS

Applicants have amended claims 1 and 11. Claim 2-10 and 12-14 are cancelled.

Support for the amendment in claims 1 and 11 reciting "inosinic acid or a derivative thereof" is found in the specification, for example at page 8, lines 5-8. Support for the amendment in claim 1 reciting "inosinic acid or a derivative thereof" is found in the specification, for example, at page 8, lines 5-8 and 18-22. Support for the amendment in claim 11 reciting "at least one unlabeled deoxyinosine 5'-triphosphate ..." is found in the specification, for example, at page 8, lines 7-10. Support for the amendment in claim 11 reciting "wherein said nucleotides or nucleotide derivatives are selected from ..." is found in the specification, for example, at page 10, line 31 through page 11, line 4. The hybridization conditions recited in claim 1 are supported by the specification, for example, page 6, line 32 to page 7, line 5.

Rejections Under 35 U.S.C. §112, first paragraph (written description)

The examiner interpreted claims 1, 3, 4 and 13 as encompassing both DNA and RNA probes and for this reason concluded that they are not supported by the specification. Claim 1 has been amended to recite a DNA probe. Claims 3, 4 and 13 have been cancelled.

The examiner rejected all of the the pending claims as failing to meet the written description requirement because, according to the examiner, the specification does not provide a "full, clear and concise" description of the claimed probes, including the number and type of nucleotides or nucleotide derivatives that would exhibit the requisite base-pairing.

Applicant has amended claim 1 to remove the limitation related to a nucleotide having "weaker affinity of hydrogen bonding ...". Claim 1 now refers to "at least one inosinic acid or derivative thereof" Applicants believe that they have provide a clear written description of such molecules by referring to inosinic acid(s) or derivative(s) and by including the limitation that the second region containing the inosinic acid(s) or derivative(s) not hybridize to the target nucleic acid molecule under the specified hybridization conditions. As the examiner knows, the prevailing case law states that a proper written description of a nucleic acid molecule be provide

either by structure (e.g., sequence) or by function combined with an understood relationship between structure and function. *University of California v. Eli Lilly & Co.* 43 USPQ2d 1400 (Fed. Cir. 1997). Moreover, the specification explains how to provide such a second region to the probe, for example, at page 9, lines 7-12 and the Examples. In addition, the specification explains that the objective probe can be prepared by carrying out the addition reaction with terminal transferase using deoxyinosine 5' -triphosphate at 2- to 10-fold excess over digoxigenin-labeled deoxyurasil 5' -triphosphate (see page 10). The person ordinary skilled in the art can create a desired probe (i.e., increase or decrease of the number of inosinic acids) changing the proportion of the nucleotides used in the reaction to balance the desired binding specificity and specific activity.

Rejections Under 35 U.S.C. §112, second paragraph (indefiniteness)

The examiner objected to the phrase "stringent conditions" in claim 1. Claim 1 has been amended to specify the conditions.

The examiner stated that claim 1 is confusing with regard to the requirements of the "second region". Claim 1 has been amended to more clearly define the second region. In particular, the first clause referring to the second region "one or more nucleotides or nucleotide derivatives..." has been deleted.

The examiner stated that claim 11 is confusing due to the lack of a modifier between limitation i) and limitation ii). Claim 11 has been amended to correct this oversight.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 11 and 14 as obvious in view of Plowman et al. taken with Mills et al.

According to the examiner, Plowman et al., at columns 15 and 23, discloses "using nucleotides and nucleotide derivatives in the development of primers/primer" Also according to the examiner, Plowman et al. teaches the use of terminal transferase at column 34.

First, Plowman et al. has described reagents and kits which are useful in various methods for detecting the SAD gene in a sample and explained that such kits could contain probes and wash reagents and reagents capable of detecting the presence of bound probe (see column 15).

These are clearly kits for using certain probes not kits for making probes as are the kits of the present claims.

Second, the reference in Plowman et al. to terminal transferase is completely unrelated to the hybridization probes and primers described by Plowman et al., much less any method or kit for preparing probes or primers. Instead, Plowman et al. simply use terminal transferase to add a polyA tail to single stranded cDNA. This use of terminal transferase is simply irrelevant to the teachings Plowman et al. regarding hybridization probes.

Mills et al. is not concerned with probes or kits for making probes. Instead Mills et al. teaches that substitution of inosine for guanosine could facilitate sequencing of RNA and DNA by reducing the tendency of single-stranded molecules to form secondary structures.

There is simply no teaching or suggestion to combine the teachings of Mills et al. regarding inosine with those of Plowman et al. Mills et al. uses inosine as a substitution for guanosine to make a substituted copy of a selected sequence. Terminal transferase could not be used in this manner. Thus, the cited references, no matter how combined, cannot be seen as suggesting a kit containing inosine or an inosine derivative and terminal transferase.

In view of the forgoing, Applicants believe that the claims are in condition for allowance.

Applicant : Tomoyasu Sugiyama et al.
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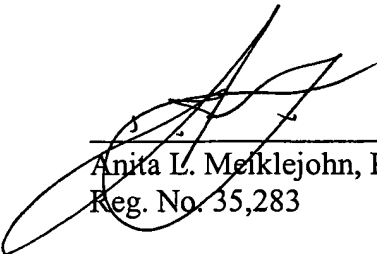
Attorney's Docket No.: 14897-080001 / H1-005PCT-
US

Enclosed is a Petition for Extension of Time with the appropriate fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: _____

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